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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,640	09/27/2001	John E. Sims	0315-C	3481

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EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	13

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,640	SIMS, JOHN E.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 1-6, 10-12 have been amended, claims 7-9 have been cancelled and claims 13-15 have been added as requested in the amendment of Paper No. 12, filed on June 06, 2003. Claims 1-6 and 10-15 are pending in the instant application.

Claims 1-6 and 10-15 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on June 06, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

5. Applicant is advised that the substitute specification submitted on June 06, 2003 has not been entered because it does not comply with § 1.125 37 C.F.R. part (b) (1), which states:
(b) A substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by:
(1) A statement that the substitute specification includes no new matter.

Appropriate action is expected.

Claim Rejections - 35 USC § 112

6. Claims 1-6 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to use the invention for reasons of record as applied to claims 1-12 in section 8 of Paper No. 10. Briefly, Claims 1-6 and 10-15 are directed to a method of treating an individual afflicted with an inflammatory and/or autoimmune disease by administration of a human IL-1 delta polypeptide. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect. Because the biological significance of the IL-1 delta of the instant invention is not disclosed, one skilled in the art clearly would not know how to use IL-1 delta.

Applicant traverses the rejection on premises that "the claimed invention is not a protein at all, but a method of using a protein". This argument has been considered but is not deemed to be persuasive. There is no disagreement that the instant claims are directed to a method of treating an individual afflicted with an inflammatory and/or autoimmune disease by administration of a human IL-1 delta polypeptide. If the claims were directed to a polypeptide itself, the instant invention would be rejected under 35 U.S.C. 101, lack of utility. However, in the instant case, because the IL-1 delta of the instant invention clearly lacks utility for those reasons of record fully explained in the earlier communication of Paper No. 10, section 8, the method of using a protein lacks enablement. The instant specification fails to provide any evidence or sound scientific reasoning to support a conclusion that administration of the instant IL-delta would have any effect on an individual and, therefore, one skilled in the art would have

to resort to a substantial amount of undue experimentation to discover how to practice the instant method, as currently claimed.

Applicant's own submission that the asserted utility of IL-delta is defined as "a soluble version of IL-delta may act as an antagonist of other, active cytokines" (page 6, last paragraph of the Response, emphasis added) additionally confirms that the instant invention was not complete, as filed, and, therefore, IL-delta clearly lacks utility in currently available form. Applicant is reminded that 35 USC § 101 clearly states that the invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. Consequently, because the utility of IL-delta at the time of filing was not established, any further experimentation to practice the method of using the novel IL-delta would reasonably be considered substantial and undue.

Applicant is advised that the references cited in the Response have only been considered in so far as they support Applicant's arguments contained therein. If Applicant wishes these references to be considered in their entirety, Applicant needs to submit the references in a form of proper IDS in accordance with 37 CFR § 1.97.

Applicant is further advised that the reliance on post-filing documents, which might disclose the biological role of the polypeptide of the instant invention, is generally considered not persuasive because this further characterization is considered to be a part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court expressed the opinion that an invention must have either an immediate obvious or fully disclosed "real world" utility. In the instant case, however, the presented publications only confirm that the biological function of IL-

delta remains unknown (see Debets et al., which describe that IL-delta acts an antagonist and agonist of the orphan IL-1 Receptor-related protein, emphasis added). Thus, the asserted utility of IL-delta polypeptides lies in the knowledge that they can modulate a physiological activity of an orphan receptor-related protein. Because the specific biological role for this orphan receptor-related protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect is unknown, modulation of the pathway through which that receptor-related protein potentially transduces its signal in response to IL-delta is not particularly useful.

In the absence of knowledge of the biological significance of this specific IL-1 delta protein, one skilled in the art would not reasonably expect that administration of IL-1 delta to an individual would result in any particular effect. Therefore, to employ IL-1 delta of the instant invention in a method of treating an individual afflicted with inflammatory or autoimmune disease would clearly be using it as the object of further research, which clearly requires one skilled in the art to partake in a substantial amount of undue experimentation in order to practice Applicant's invention as currently claimed.

7. Claims 1-6 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for those reasons of record in section 8 of Paper No. 10.

Applicant submits that "the specification, in combination with the knowledge of those skilled in the art, teaches how to make IL-1 delta polypeptides (including polypeptides that are 80% identical to that of SEQ ID NO: 4 and that possess the function of being able to block an

inflammatory response) and the specification teaches how to test for blocking activity in an inflammatory response, the specification enables the subject claims" (page 7, last paragraph of the Response going to page 8). These arguments have been fully considered but are not deemed to be persuasive for the reasons that follow.

The instant rejection is not lack of enablement but lack of written description rejection. Claims 1-6, as amended, are directed to a method of treating an individual afflicted with an inflammatory and/or autoimmune disease by administration of a IL-1 delta polypeptide encoded by DNAs that hybridize to the DNA of SEQ ID NO: 3 or by administration of polypeptides that are 80% identical to the polypeptide of SEQ ID NO: 4 wherein the polypeptides block an inflammatory response. The instant specification lacks a written description of the entire genus of proteins, which are encompassed by these claims because the claims are not limited to a method of treatment by administration of a protein with a specific amino acid sequence. The claims only require the polypeptide to share some degree of structural similarity to the isolated protein of SEQ ID NO: 4 and yet to have the activities possessed by the novel IL-delta. Furthermore, the instant application fails to recite any relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for reciting the conditions of hybridization in parenthesis. By using parenthesis, it appears that the conditions recited are exemplarily, which makes the claimed subject matter indefinite.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. ONC

JOHN ULM
PRIMARY EXAMINER
GROUP 1800